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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,627	07/29/2003	Joseph C. Malcy	ACRY4.CIP	9066
6980	7590	09/07/2007	EXAMINER	
TROUTMAN SANDERS LLP			AHMED, HASAN SYED	
600 PEACHTREE STREET , NE			ART UNIT	
ATLANTA, GA 30308			PAPER NUMBER	
			1615	
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			09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,627	Applicant(s) MALEY ET AL.	
	Examiner Hasan S. Ahmed	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-17 and 21-24 is/are pending in the application.
 4a) Of the above claim(s) 1, 3, 4, and 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of Applicants' request for continued examination and amendment, both filed on 22 June 2007.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 June 2007 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 11-17 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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As amended, the instant claim set recites the limitations "pressure sensitive adhesive-free" and "in an amount effective to treat." After carefully examining the instant disclosure, the examiner respectfully submits that support for these amendments is lacking and the addition of said limitation is new matter.

*

2. Claims 11-17 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for the creation of a diffusion gradient between the claimed composition and nail structures, as set forth in examples 3, 6, and 7 of the instant specification, is not enabled for the creation of a diffusion gradient between the claimed composition and all dermal structures, as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation "dermal structure" is extremely broad and encompasses a wide variety of tissue types.

According to the instant specification, a dermal structure includes skin, hair, hair follicles, cornea, sclera, organ linings, pleural coverings, dura, toenails, fingernails, hooves, horns, mucous membranes, and other cellular structures made from epithelial cells or keratinized structures (see paragraph 0003). To this end, given that the instant claims are drawn creation of a diffusion gradient between the claimed composition and all dermal structures, the examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is

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concerned with only a limited subclass of dermal structures, such as the ones set forth in 3, 6, and 7 of the instant specification, and an ordinary practitioner would need to undergo undue experimentation in order to develop a diffusion gradient between the claimed composition and all dermal structures without guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "dermal structures."

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Asmus (U.S. Patent No. 5,270,358).

Asmus discloses a transdermal composition comprising a hydrogel (see col. 2, lines 32-38). The disclosed composition is the instant composition as claimed:

- the hydrogel of instant claim 11 (see col. 6, line 31);
- the active agent of instant claim 11 (see col. 12, lines 12-26);
- the humectant (e.g. glycerol) of instant claim 11 (see col. 9, lines 61-62);
- the moisture content of instant claim 11 (see col. 3, line 10; examples 87 and 88);

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- the organic acid of instant claim 11 (see col. 12, line 42 – i.e. antibiotic; e.g. penicillin, which is a weak organic acid);
- the moisture management system (as disclosed in pages 23-24 of the Specification, i.e. guar gum) of instant claim 12 (see col. 6, line 68);
- the attachment element (adhesive) of instant claim 13 (see col.2, lines 32-38);
- the polyacrylamide of instant claim 14 (see col. 6, line 66);
- the antibacterial (antimicrobial) compounds of instant claim 15 (see col. 12, lines 12-26);
- the glycerol of instant claim 16 (see col. 9, lines 61-62); and
- the moisture content of instant claim 17 (see col. 3, line 10; examples 87 and 88).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (U.S. Patent No. 5,270,358).

Asmus discloses a transdermal composition comprising a hydrogel (see above).

Asmus explains that the disclosed invention provides utility for skin adhesive applications (see col. 4, line 26).

While Asmus does not explicitly teach the percentages of instant claims 21-23, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

* * * * *

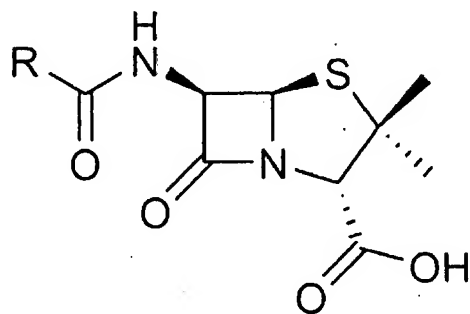
Response to Arguments

Applicants' arguments filed 22 June 2007 have been fully considered but they are not persuasive.

1. Applicants argue that, "...Asmus does not disclose the use of any organic acids as active ingredients and does not teach an amount that would be effective to treat a condition of a dermal structure." See remarks, page 7.

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Examiner respectfully submits that Asmus discloses antibiotics as active ingredients (see col. 12, line 42). Penicillin, which is a common antibiotic, is a weak organic acid.



Penicillin

Additionally, the limitation, "an amount that would be effective to treat a condition of a dermal structure" is deemed to be new matter (see 35 USC 112 rejection, above).

2: Applicants argue that, "[i]n Asmus, there is no teaching of providing moisture to the application site, and in fact, there is clear teaching against providing moisture to the site..." See remarks, page 8.

Examiner respectfully submits that the Asmus reference discloses each and every element of the instant claims vis-à-vis the broad construction of the instant claims.

As currently constructed, claim 11 does not specify the source of moisture at the dermal structure or whether there is a direct correlation between the diffusion gradient and moisture at the dermal structure. The claim language lacks the subordinating conjunction needed to establish a causal link between the diffusion gradient and moisture at the dermal surface.

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Furthermore, the claim does not specify the extent of moisture at the dermal structure; there is no indication in the claim language that the dermal structure will be subject to increased moisture as a result of the diffusion gradient, as opposed to ambient moisture resulting from water content in the claimed composition. The Asmus reference discloses water content within the range recited in instant claim 17 (see examples 87 and 88). Thus, the article disclosed by Asmus will provide some level of moisture to the dermal structure, as instantly claimed. As such, examiner respectfully submits that the Asmus reference anticipates the instant application, as claimed.

In addition, applicants have only shown a transfer of moisture between the claimed composition and nail structures, which are hydrophilic (see 35 USC 112 rejection, above). The Asmus reference recites intended use of the disclosed invention on skin surfaces (which are hydrophobic), not on nail surfaces. Applicants' composition, as claimed, is the same as the prior art. As, claimed, applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433. Examiner respectfully submits that if the Asmus invention were applied to a nail structure, moisture would transfer from the composition to the nail structure.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


HUMERA N. SHEIKH
PRIMARY EXAMINER